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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,845	02/26/2002	Daniel Armstrong	ARM-1A	8192

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EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 03/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,845

Applicant(s)

ARMSTRONG, DANIEL

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8-13,15 and 17-30 is/are pending in the application.
- 4a) Of the above claim(s) 18-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8-13,15,17 and 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed January 03, 2006 ("Amendment") have been fully considered but they are not persuasive.

Applicant asserts, "The isoelectric focusing process of the present invention focuses microbes or other particles by means of an electric field." See page 17 of the Amendment. This is not conventional isoelectric focusing, which is all Applicant has support for: "The capillary isoelectric focusing is conducted in a conventional manner using conventional equipment." See Applicant's specification, page 15, third paragraph. In conventional isoelectric focusing charged particles are moved by an electric field along a pH gradient until their isoelectric points are reached. At the isoelectric point for each charged particle, the particle will be focused because it has no net charge. In conventional isoelectric focusing particles are not focused because of the electric field, but because of a chemical change, such as loss or gain of H^+ . A review article describing the principles and some applications of isoelectric focusing is provided with this Office action (Liu et al. "Review: Capillary isoelectric focusing as a tool in the examination of antibodies, peptides and proteins of pharmaceutical interest").

Applicant asserts, "The relatively high voltage [20kV] of the present invention gives the fluid inside the capillary a flat flow velocity profile." See page 17 of the Amendment. There is no mention of a voltage range in the claims. Furthermore, there is no mention in the original disclosure of such a result.

Applicant asserts, "...Fuhr does not focus microbes using an electric field." See page 17 of the Amendment. Neither does Applicant. As discussed above conventional isoelectric focusing does not focus microbes using an electric field. In fact, once focused the microbes should not be influenced by the field (at least not in terms of movement) since they have no net charge.

Applicant asserts, "Although Fuhr does employ a voltage, the voltage is between 1-10 V..." See page 18 of the Amendment. As noted above, there is no mention of a voltage range in the claims.

Claim Rejections - 35 USC § 112

2. Claims 1, 3-6, 8-13, 15, 17, 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to

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reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Note that claims 22-30 were not part of the original disclosure, but added by the amendment of May 10, 2005. All of the independent claims require performing isoelectric focusing on sample in a moving fluid. However, Applicant's specification only discloses conventional isoelectric focusing: "The capillary isoelectric focusing is conducted in a conventional manner using conventional equipment." See Applicant's specification, page 15, third paragraph. Conventional isoelectric focusing does not involve moving fluid while focusing the sample, although the fluid may be moved *after* the sample components have been focused (mobilization). See, for example, the first and second paragraphs in section 1.10 *Coated capillaries and salt mobilization. Background* on page 173 of Liu et al. "Review: Capillary isoelectric focusing as a tool in the examination of antibodies, peptides and proteins of pharmaceutical interest. Applicant's specification actually teaches away from moving fluid while focusing the sample components: "Samples were injected into the tube ... followed by a second injection of ampholyte for 129 seconds. *After focusing* for 5 min (voltage 20kV) samples were *mobilized with low pressure* (0.5psi) rinse while the 20 kV voltage was maintained [emphasis added]." See first full paragraph on page 28. Thus, there is no support in the original disclosure for moving fluid during isoelectric focusing.

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3. Claims 1, 3-6, 8-13, 15, 17, and 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. All of the independent claims require performing isoelectric focusing. Applicant's specification only discloses conventional isoelectric focusing: "The capillary isoelectric focusing is conducted in a conventional manner using conventional equipment." See Applicant's specification, page 15, third paragraph. In conventional isoelectric focusing charged particles are moved by an electric field along a pH gradient until their isoelectric points are reached. At the isoelectric point for each charged particle, the particle will be focused because it has no net charge. In conventional isoelectric focusing particles are not focused because of the electric field, but because of chemical change, such as loss or gain of H^+ . Applicant now states, though, 'The "focusing" is achieved by employing an optimum voltage in the electric field which promotes electrophoretic mobility.' See page 17 of the Amendment. Claim 1, for example, requires "isoelectric focusing said one or more microbes/cells in said moving fluid by means of an electric field so as to focus said one or more microbes/cells in said moving fluid..." Applicant argues that in contrast to Fuhr in Applicant's invention it is the electrical field that focuses the sample components. Applicant thus argues for a new interpretation of "isoelectric focusing" for which he has no support in the original disclosure.

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4. Claims 1, 3-6, 8-13, 15, 17, and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Independent claims 1, 6, 10, and 15 require focusing microbes/cells by means of an electric field during the isoelectric focusing *and* focusing the microbes by a dilute water-soluble polymer during the isoelectric focusing. As discussed in the previous paragraph there is no support for focusing microbes/cells by means of an electric field during the isoelectric focusing. There is also no support for focusing the microbes by a dilute water-soluble polymer during the isoelectric focusing, even for conventional isoelectric focusing as conventionally understood. Applicant's original disclosure does teach using a dilute water-soluble polymer, but only for *capillary electrophoresis*: "When employing capillary electrophoresis, a water soluble polymer must be present." See page 14 of the specification. Applicant clearly distinguishes between *capillary electrophoresis* embodiments and *capillary isoelectric focusing* embodiments: "The capillary isoelectric focusing has an amphylote that is chosen specifically for focusing the microbe/cell in the fluid and will not lyse the microbe." See page 15 of the specification. There is no mention or suggestion in the original disclosure of using a dilute water-soluble polymer during isoelectric focusing.

Claim Objections

5. Claim 1 is objected to because of the following informality:

a) Claim 1: it appears that "microbes" in lines 2 and 17 should be

-- microbes/cells -- .

b) Claim 4 : « analysis » should be -- analyzing --

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 3-6, 8-13, 15, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a) Claim 1 is inconsistent because step (b) requires the microbes/cells to be focused by means of an electric field during the isoelectric focusing, but the last paragraph of the claim requires the microbes to be focused by a dilute water-soluble polymer during the isoelectric focusing. This is especially inconsistent because the dilute water-soluble polymer is in a moving fluid. How can the microbes/cells be focused by an electric field, that is, held in place, and also focused in a dilute water-soluble polymer that is moving? That is how can the microbes/cells be stationary and moving at the same time?

Similarly, independent claims 6, 10, 15 require during the isoelectric focusing focusing the microbes by means of an electric field and focusing the microbes with a dilute water-soluble polymer in the moving fluid.

8. Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 103

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Claims 26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhr et al. (US 6,833,061 B1) ("Fuhr").

Fuhr discloses a process for separating and identifying intact microbes while maintaining the microbes intact comprising

(a) obtaining a sample comprising one or more intact particles (implied since a sample is separated);

(b) introducing the sample into a passageway having a moving fluid therein (col. 1:8-13 and col. 6:7-34 – note guiding fluid);

(c) isoelectric focusing the one or more particles in the moving fluid by means of an electric field so as to focus the one or more particles in the moving fluid and to separate one from another and from any other components in the sample while maintaining the particles intact (Figure 1; col. 5:8-9; and col. 6:35 – col. 7:5); and

analyzing the separated intact particles so as to identify the particles (col. 7:1-5 and col. 8:59-67),

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wherein the moving fluid comprises an ampholyte that focuses the microbes/cells in the passageway during the isoelectric focusing step (col. 1:8-13; col. 6:3-6; and col. 4:16-37).

While Fuhr does not have an example in which the particles are intact microbes or cells it would have been obvious to one with ordinary skill to use his method to isoelectrically separate microbes or cells because Fuhr clearly contemplates such a use:

Isoelectric separation according to the invention can be implemented with ampholytic molecules or all other synthetic or biological particles (especially cells or viruses) that exhibit electrical characteristics like those of ampholytic molecules, in particular a net charge or charge density that is a pH function of the surroundings [emphasis added]. See col. 4:16-21.

The method according to claim 1, wherein the particles to be separated comprise ampholytic molecules or other particles, synthetic particles or biological cells, viruses, or other biological objects whose exhibit electrical characteristics correspond to the electrical characteristics of ampholytic molecules [emphasis added]. *Claim 2.*

The invention concerns methods and devices for isoelectric separation of particles whose charge characteristics depend on the pH value of a guiding fluid, especially for separating ampholytic suspended particles, colloids or biological cells. The invention concerns in particular the separation of such particles from a guiding fluid flow. [emphasis added] See col. 1:8-13.

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11. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fuhr et al. (US 6,833,061 B1) ("Fuhr") in view of Dürr (US 5,723,031) (Dürr) and English language translation of Tollet et al. (FR2468120) ("Tollett").

Fuhr discloses a process for separating and identifying intact microbes while maintaining the microbes intact comprising

(a) obtaining a sample comprising one or more intact particles (implied since a sample is separated);

(b) introducing the sample into a passageway having a fluid therein (col. 1:8-13 and col. 6:7-34 – note guiding fluid);

(c) isoelectric focusing the one or more particles in the moving fluid by means of an electric field so as to focus the one or more particles in the moving fluid and to separate one from another and from any other components in the sample while maintaining the particles intact (Figure 1; col. 5:8-9; and col. 6:35 – col. 7:5); and

analyzing the separated intact particles so as to identify the particles (col. 7:1-5 and col. 8:59-67),

wherein the moving fluid comprises an ampholyte that focuses the microbes/cells in the passageway during the isoelectric focusing step (col. 1:8-13; col. 6:3-6; and col. 4:16-37).

While Fuhr does not have an example in which the particles are intact microbes or cells it would have been obvious to one with ordinary skill to use his method to isoelectrically separate microbes or cells because Fuhr clearly contemplates such a use:

Isoelectric separation according to the invention can be implemented with ampholytic molecules or all other synthetic or biological particles (especially cells or viruses) that exhibit electrical characteristics like those of ampholytic molecules, in particular a net charge or charge density that is a pH function of the surroundings [emphasis added]. See *col. 4:16-21*.

The method according to claim 1, wherein the particles to be separated comprise ampholytic molecules or other particles, synthetic particles or biological cells, viruses, or other biological objects whose exhibit electrical characteristics correspond to the electrical characteristics of ampholytic molecules [emphasis added]. *Claim 2*.

The invention concerns methods and devices for isoelectric separation of particles whose charge characteristics depend on the pH value of a guiding fluid, especially for separating ampholytic suspended particles, colloids or biological cells. The invention concerns in particular the separation of such particles from a guiding fluid flow. [emphasis added] See *col. 1:8-13*.

Fuhr does not mention having the microbes be from an organism stricken with a disease caused by the microbes and diagnosing a disease caused by the microbes.

Dürr and Tollet disclose performing electrophoresis on microbes from an organism stricken with a disease caused by the microbes and diagnosing a disease caused by the microbes. See in Dürr the abstract; col. 2:43-56; 3:3-8; col. 3:30-34 and in Tollet the first paragraph on page 1 and the third and fourth paragraph on page 8. it would have been obvious to one with ordinary skill in the art at the time of the invention to perform electrophoresis on microbes from an organism stricken with a disease caused by the microbes and diagnosing a disease caused by the microbes as taught by

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Dürr and Tollet in the invention of Fuhr because as then diseased patient can be appropriately treated and monitored.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguera
Primary Examiner
AU 1753
March 16, 2006